

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Marija BOGATAJ, et al.
Application No. 10/599.289
Filing Date:
International Filing: March 24, 2005
Confirmation No. 6552
Title: Gastroresistant Pharmaceutical Dosage Form Comprising
N-(2-(2-Phthalimidoethoxy)-Acetyl)-L-Alanyl-D-Glutamic Acid
(LK-423)
Group Art Unit:

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS
UNDER 35 U.S.C. 371
IN THE UNITED STATES DESIGNATED/ELECTED OFFICE
(DO/EO/US)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notification of Missing Requirements under 35 U.S.C. §371 in the United States Designated/Elected Office (DO/EO/US) mailed February 23, 2009 (copy attached), Applicants enclose herewith executed Declaration and Power of Attorney documents as follows:

- 1) Declaration executed by Marija BOGATAJ on 11 October 2006, Ales MRHAR on 11 October 2006, Manica CERNE on 20 October 2006, Doris TIBAUT on 20 October 2006, Anton STALC on 3 November 2006, Uros URLEB on 29 October 2006, Tatjana MATEOVIC on 11 October 2006, Greta COF on 11 October 2006, Janez KERC on 23 October 2006, and Rok DREU on 11 October 2006;
- 2) Declaration executed by Fumio YONEDA on 26 September 2006, and Shizuko MURAOKA on 26 September 2006, and;
- 3) Declaration executed by administrator for estate of Anton LAVRIC on July 6, 2009.

Finally, the §371 Formalities Letter of February 23, 2009, requested that a sequence listing to be submitted along with the Oath/Declaration and Fees. However, the present application is not believed to contain any biological sequence disclosure or other information sufficient to require the submission of a formal or any other sequence listing. The mere mention of matters involving biological processes, in general, does not oblige Applicants to disclose any sequences or the like. Therefore, no sequence listing need be submitted, and the letter in this regard is respectfully believed to have been sent in error. In this regard, Ed LaRose of our office spoke with the USPTO PCT help desk regarding the 371 Formalities Letter and was advised to simply note this in our response as follows:

Statement

There are no biological sequences contained within the present application, therefore, contrary to the §371 Formalities Letter of February 23, 2009, there is no need to submit a genetic or other sequence listing in this case.

The above is believed to constitute a full and complete response to the USPTO's Notification of Missing Requirements Under 35 U.S.C. §371 in the United States Designated/Elected Office (DO/EO/US). Please charge our Deposit Account No. 12-2355 for the surcharge fee of \$130.00, and for the three month extension fee of \$1,110.00, for a total of \$1,240.00, for this response. If this amount is insufficient, or is incorrect for any reason, please charge any deficiencies or credit any overage to our Deposit Account No. 12-2355.

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: /Mark S. Graham/

Mark S. Graham
Registration No. 32,355

Date: July 20, 2009
P.O. Box 1871
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E-filing



UNITED STATES PATENT AND TRADEMARK OFFICE

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U.S. APPLICATION NUMBER NO. 10/599,289	FIRST NAMED APPLICANT MARIJA BOGATAJ	ATTY. DOCKET NO. 33705-US-PCT
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72554
SANDOZ INC
506 CARNEFIE CENTER
PRINCETON, NJ 08540

RECEIVED

MAR 04 2009

LUEDEKA, NEELY & GRAHAM, P.C.

INTERNATIONAL APPLICATION NO. PCT/EP2005/003175	
I.A. FILING DATE 03/24/2005	PRIORITY DATE 03/26/2004

CONFIRMATION NO. 6552
371 FORMALITIES LETTER



Date Mailed: 02/23/2009

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371
IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Priority Document
- Copy of the International Application filed on 09/25/2006
- Copy of the International Search Report filed on 09/25/2006
- Copy of Article 19 Amendments filed on 09/25/2006
- Preliminary Amendments filed on 09/25/2006
- Information Disclosure Statements filed on 09/28/2006
- Oath or Declaration filed on 09/25/2006
- U.S. Basic National Fees filed on 09/25/2006
- Priority Documents filed on 09/25/2006
- Specification filed on 09/25/2006
- Claims filed on 09/25/2006
- Abstracts filed on 09/25/2006
- Drawings filed on 09/25/2006



The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and International filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.
- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15,

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Resp To Missing
Requirements Due
DATES DOCKETED 4-23-09
ATTY.

1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patent Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patent Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

VONDA M WALLACE

Telephone: (703) 308-9140 EXT 225

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